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| APPLICATION NO | ).        | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|----------------|-----------|-------------|--------------------------|---------------------|------------------|--|
| 10/720,909     |           | 11/24/2003  | Roland Janzen            | DCS-9151            | 5291             |  |
| 34500          | 7590      | 05/17/2006  |                          | EXAM                | EXAMINER         |  |
| DADE BI        | EHRING    | INC.        | VENCI, DAVID J           |                     |                  |  |
| LEGAL D        |           |             |                          | APTIBUT             | DARED MIMEDED    |  |
| 1717 DEE       | RFIELD R  | .OAD        |                          | ART UNIT            | PAPER NUMBER     |  |
| DEERFIE        | LD, IL 60 | 0015        | 1641                     |                     |                  |  |
|                |           |             | DATE MAIL ED: 05/17/2006 |                     |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <i>≈</i> 4   |  |  |   |
|--|--|--|---|
|  | Application No.  | Applicant(s)   |   |
| Advisory Action  | 10/720,909   | JANZEN ET AL.  |   |
| Before the Filing of an Appeal Brief   | Examiner   | Art Unit   |   |
|  | David J. Venci   | 1641   |   |
| The MAILING DATE of this communication appe  | ears on the cover sheet with the c   | correspondence address   |   |
| THE REPLY FILED March 27, 2006 FAILS TO PLACE THIS A   |  |  |   |
| <ol> <li>The reply was filed after a final rejection, but prior to or or this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a Not a Request for Continued Examination (RCE) in compliant time periods:</li> <li>The period for reply expires 3 months from the mailing date.</li> </ol>                       | wing replies: (1) an amendment, aft office of Appeal (with appeal fee) in one ce with 37 CFR 1.114. The reply more of the final rejection. | idavit, or other evidence,<br>compliance with 37 CFR 4<br>ust be filed within one of t | which<br>41.31; or (3)<br>the following |
| b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire I Examiner Note: If box 1 is checked, check either box (a) or TWO MONTHS OF THE FINAL REJECTION. See MPEP 7   | later than SIX MONTHS from the mailing (b). ONLY CHECK BOX (b) WHEN THE 106.07(f).   | g date of the final rejection.<br>E FIRST REPLY WAS FILED                              | O WITHIN                                |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of ex under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office late may reduce any earned patent term adjustment. See 37 CFR 1.704(b) NOTICE OF APPEAL | dension and the corresponding amount<br>shortened statutory period for reply orig<br>r than three months after the mailing da              | of the fee. The appropriate of inally set in the final Office as                       | extension fee ction; or (2) as          |
| 2. The Notice of Appeal was filed on April 11, 2006. A brief date of filing the Notice of Appeal (37 CFR 41.37(a)), or a appeal. Since a Notice of Appeal has been filed, any repl AMENDMENTS  | any extension thereof (37 CFR 41.3   | 7(e)), to avoid dismissal of   | of the                                  |
| The proposed amendment(s) filed after a final rejection,  (a) They raise new issues that would require further co  (b) They raise the issue of new matter (see NOTE belo  (c) They are not deemed to place the application in be appeal; and/or  (d) They present additional claims without canceling a NOTE: (See 37 CFR 1.116 and 41.33(a)).                                   | onsideration and/or search (see NO ow);<br>tter form for appeal by materially re<br>corresponding number of finally rej                    | TE below); ducing or simplifying the i   |   |
| 4. The amendments are not in compliance with 37 CFR 1.1  |  | mpliant Amendment (PTC   | OL-324).                                |
| 5. Applicant's reply has overcome the following rejection(s)   | ——————————————————————————————————————   |  |   |
| <ol> <li>Newly proposed or amended claim(s) would be a<br/>non-allowable claim(s).</li> </ol>  | llowable if submitted in a separate,   | timely filed amendment c   | anceling the                            |
| 7.  For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is pro The status of the claim(s) is (or will be) as follows: Claim(s) allowed: <u>none</u> . Claim(s) objected to: <u>none</u> . Claim(s) rejected: <u>1-8,12 and 14-16</u> . Claim(s) withdrawn from consideration: <u>9-11 and 17-21</u> .                          | ☐ will not be entered, or b)   | ll be entered and an expla   | anation of                              |
| AFFIDAVIT OR OTHER EVIDENCE  |  |  |   |
| <ol> <li>The affidavit or other evidence filed after a final action, be<br/>because applicant failed to provide a showing of good an<br/>was not earlier presented. See 37 CFR 1.116(e).</li> </ol>  |  |  |   |
| <ul> <li>9.  The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to a showing a good and sufficient reasons why it is necessar</li> <li>10.  The affidavit or other evidence is entered. An explanation</li> </ul>   | overcome <u>all</u> rejections under appe<br>y and was not earlier presented. S  | al and/or appellant fails to<br>ee 37 CFR 41.33(d)(1).                                 | provide a                               |
| REQUEST FOR RECONSIDERATION/OTHER  | 5. alo otatao of the olalino diter e   | , io boion of attached.  |   |

13. Other: \_\_\_\_. LONG V. LE 0/2/06 SUPERVISORY PATENT EXAMINER

12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_

11. 🛛 The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

**TECHNOLOGY CENTER 1600** 

See Continuation Sheet.

## Continuation of 11:

Claims 1-8, 12 and 14-16 are product claims. Claims 1-8, 12 and 14-16 are not method claims. Accordingly, in claim 1, the recited claim language "dissociated" first binding species is interpreted as a statement that merely states an intended use or intended result of the claimed product invention. Similarly, the recited claim language of binding partners capable of selectively binding "dissociated" first binding species is interpreted as a statement that merely states an intended use or intended result of the claimed product invention. In addition, the recited claim language of binding "dissociated" first binding species without detrimentally affecting the signal strength of said assay is not afforded patentable weight because the claim language is interpreted as a statement that merely states an intended use or intended result of the claimed product invention.

The intended use of the claimed product invention must result in a structural difference between the claimed product invention and the prior art in order to patentably distinguish the claimed product invention from the prior art. If the prior art structure is capable of performing the intended use or intended result, then the prior art meets the claim.

Here, the prior art teachings of Ullman et al. describe a product wherein a "binding partner" binds to a "binding species" (see col. 35, lines 36-38; col. 37, lines 28-35).

Applicants' reliance on "lines 33-34" of Ullman et al., which allegedly states that "preferably the photosensitizer and chemiluminescent molecules are incorporated into particles and the sbp (specific binding partner) members are attached to the particles" (see Applicants' AMENDMENT AFTER FINAL, paragraph bridging pp. 3-4, second sentence) does not appear to address the passages in Ullman et al. that were cited in the prior Office Action, and its relevance to the instant rejection is not clear.

Applicants' reliance on an allegedly analogous situation of an "antibody specific to hCG" versus an "antibody specific to cyclosporine" is not clear. Examiner requests that Applicants further expound this analogy.